

NEW RULE – WORKING DRAFT

PRODUCTION AND SALE OF COTTAGE FOOD PRODUCTS

NEW RULE I PURPOSE (37.110.50X) (1) The purpose of this subchapter is to provide rules in addition to the provisions stated in 50-50-102, 50-50-116, 50-50-117, and 50-50-121, MCA, so that cottage food products may be safely produced for the public in approved home kitchens.

NEW RULE II DEFINITIONS (37.110.50X) In addition to the definitions contained in 50-50-102, MCA, the following definitions apply to this subchapter:

- (1) "Baked goods" means breads, candies, cookies, pastries, and pies that are non-potentially hazardous because they are non-time temperature controlled for safety.
- (2) "Cottage food operator" means a person registered with the regulatory authority to operate a cottage food operation.
- (3) "Approved" means acceptable to the regulatory authority based on their determination of conformity with principles, practices, and generally recognized standards that protect public health.

NEW RULE III (37.110.503) APPROVED COTTAGE FOOD PRODUCTS

(1) Only those products approved by the department and listed in the registration may be produced by a cottage food operation. A cottage food operation is allowed to produce the following food items as long as they are a non-potentially hazardous food:

- (a) products that may be cooked in an oven including:
 - (i) loaf breads, rolls, biscuits, quick breads, and muffins;
 - (ii) cakes including celebration cakes such as birthday, anniversary, and wedding cakes;
 - (iii) pastries and scones;
 - (iv) cookies and bars;
 - (v) crackers;
 - (vi) cereals, trail mixes, and granola;
 - (vii) pies, except that custard style pies, pies with fresh fruit that is unbaked, or pies that require refrigeration after baking are not approved;
 - (viii) nuts and nut mixes; and
 - (ix) snack mixes;
- (b) standardized jams, jellies, preserves, and fruit butters as identified under 21 CFR, Part 150, subject to the following:
 - (i) fresh picked or harvested fruits from noncommercial sources are allowed for use;
 - (ii) fresh fruits may be frozen in a household freezer and used at a later time;
 - (iii) all recipes must have a cook step included such as a hot fill or hot water bath, and freezer or refrigerator-style products are not approved;
 - (iv) all jams, jellies, preserves and fruit butters must be sealed in containers that are sterilized prior to filling; and
 - (v) paraffin wax is not allowed for sealing;
- (c) repackaged, commercially dried fruit or vegetables from an approved source as described in [New Rule VIII(2)], or fresh fruits that:
 - (i) have a natural pH below 4.6, specifically: apples, apricots, grapefruit, lemons, limes, mangos, nectarines, oranges, peaches, plums, pomegranates, tangerines, blackberries, blueberries, cherries, cranberries, currants, gooseberries, grapes, raspberries, strawberries, and huckleberries; and
 - (ii) are dried by cottage food operators with the following methods:

(A) during the fruit drying process the fruit must reach 160° Fahrenheit within an hour of processing the fruit;

(B) the fruit must then maintain 140° Fahrenheit for the remainder of the drying process;

(C) dried fruit may not be packaged using any method of reduced oxygen packaging, including vacuum packaging.

(d) dry herb combining and packaging, and seasoning and mixture combining; examples of which are dry bean soup mixes, dry teas and coffees, and spice seasonings;

(e) popcorn, popcorn balls, cotton candy;

(f) fudge, candies, and confections that require a cook step;

(g) molded chocolate using commercial chocolate melts; and

(h) honey.

(2) The following provisions apply to the production of cottage food products:

(a) fresh picked or harvested fruits from noncommercial sources are allowed in baked good products;

(b) fresh fruits can be frozen and used at a later time as long as there is a cook step in the recipe; and

(c) all frostings or glazes must have a cook step or be made with ingredients (such as a large amount of sugar) that when combined are stable at room temperature.

(3) Other products may be approved on a case-by-case basis by the department in consultation with the local health authority of the county in which the cottage food operator is registered.

NEW RULE IV LABELING (37.110.50X) (1) Cottage food operations must adhere to the labeling requirements outlined in 50-50-116, MCA.

(2) The following is representative of a label meeting the requirements of (1):

MADE IN A HOME KITCHEN THAT IS NOT SUBJECT TO RETAIL FOOD
ESTABLISHMENT REGULATIONS OR INSPECTIONS

Chocolate Chip Cookies

Net Wt. 8oz (227g)

Ingredients: Enriched flour (Wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter, butterfat (milk), soy lecithin as an emulsifier), walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda.

Contains: Wheat, eggs, milk, soy, walnuts.

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(3) The department may allow large cakes or a container of bulk products to be handled and labeled in the following manner:

(a) be protected from contamination during transportation to the consumer; and

(b) have a product label sheet with all the required information as listed in (1) that is that is provided to the consumer.

NEW RULE V COTTAGE FOOD OPERATOR HEALTH (37.110.50X) (1) Cottage food operators must not manufacture cottage food products (for example, working with exposed food; working with cleaning equipment, utensils, and linens; or working with unwrapped single-service or single-use articles) while experiencing the following symptoms:

- (a) vomiting;
- (b) diarrhea;
- (c) jaundice;
- (d) sore throat with fever;
- (e) a lesion containing pus such as a boil or infected wound that is open or draining and is:

- (i) on the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
- (ii) on exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
- (iii) on other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;
- (f) symptoms of any of the following illnesses as diagnosed by a health practitioner:
 - (i) norovirus;
 - (ii) hepatitis A virus;
 - (iii) shigella spp.;
 - (iv) shiga toxin-producing escherichia coli;
 - (v) salmonella typhi; or
 - (vi) nontyphoidal salmonella.

(2) A cottage food operator experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth must not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

NEW RULE VI PERSONAL CLEANLINESS (37.110.50X) (1) Cottage food operators must keep their hands and exposed portions of their arms clean.

(2) Cottage food operators must use the following procedure in order to keep their hands and exposed portions of their arms clean:

- (a) rinse under clean, running warm water;
- (b) apply an amount of soap;
- (c) rub together vigorously for at least 10 to 15 seconds while:
 - (i) paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
 - (ii) creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;
- (d) thoroughly rinse under clean, running warm water; and
- (e) immediately follow the cleaning procedure with thorough drying using a single use towel.

(3) Cottage food operators must clean their hands and exposed portions of their arms immediately before engaging in food preparation, which includes working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles, and:

- (a) after touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (b) after using the toilet room;
- (c) after caring for or handling service animals, household pets, or aquatic animals;
- (d) after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- (e) after handling soiled equipment or utensils;

(f) during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;

(g) when switching between working with raw food and working with ready-to-eat food;

(h) before donning gloves to initiate a task that involves working with food; or

(i) after engaging in other activities that contaminate the hands.

(4) Cottage food operators must keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. Unless wearing intact gloves in good repair, a cottage food operator may not wear fingernail polish or artificial fingernails when working with unpackaged food.

(5) Except for a plain ring such as a wedding band, cottage food operators may not wear jewelry on their arms and hands while preparing food, including medical information jewelry.

(6) Cottage food operators must wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

NEW RULE VII HYGIENIC PRACTICES (37.110.50X) (1) A cottage food operator must not eat, drink, or use any form of tobacco in the registered area of the domestic residence while preparing a cottage food, or where the contamination of exposed food, clean equipment, utensils, and linens, unwrapped single-service and single-use articles, or other items needing protection can result.

(2) Cottage food operators must provide a barrier between the registered area of their domestic residence and all pets while preparing and packaging cottage food items.

NEW RULE VIII (37.110.510) MANUFACTURE OF COTTAGE FOOD PRODUCTS (1)

Cottage food products must be safe, unadulterated, honestly presented, and:

(2) Food must be obtained from approved sources, including:

(a) must be offered for human consumption in a way that does not mislead or misinform the consumer;

(b) food or color additives and colored overwraps may not be used to misrepresent the true quality of a cottage food product, although dying cookies or other similar products and/or wrapping them for a theme such as a green cookie for St. Patrick's Day or a popcorn ball wrapped in red plastic for Christmas is allowed.

(c) In many cases local farm products are considered approved sources; consult with your local health authority to make determinations on a case-by-case basis.

(3) Eggs and dairy ingredients must be stored under refrigeration.

(4) Upon receiving food packages from an approved source, food packages must be maintained in good condition and protect the integrity of the contents so the food is not exposed to adulteration or potential contaminants.

(5) Cottage food operators must minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.

(6) Cottage food operators may not contact exposed, ready-to-eat food with their bare hands, and must use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.

(7) A cottage food operator may not use a utensil more than once to taste cottage food products or ingredients that are to be sold or served.

(8) Food contact surfaces must be easily cleanable.

(9) Food must only contact surfaces of equipment and utensils that are cleaned and sanitized as specified:

(a) equipment food-contact surfaces and utensils must be clean to sight and touch;

(b) food-contact surfaces of cooking equipment and pans must be kept free of encrusted grease deposits and other soil accumulations.

(c) To the extent practicable, cottage food manufacturers should either dip utensils,

dishes, and equipment in a 100 ppm chlorine bleach solution (or other approved sanitizer) and allow to air dry, or use the sanitizing cycle of a dishwasher.

(10) Toxic chemicals such as household cleaners, concentrated bleach, and pesticides must be stored in a way that will not contaminate food, food-preparation areas, and food-contact surfaces.

NEW RULE IX (37.110.511) REGISTRATION REQUIREMENTS

(1) Registration must follow the requirements provided in 50-50-117, MCA.

(2) The registrant must provide their name, mailing address, phone number, and e-mail address.

(3) The registrant must provide a detailed description of cottage food product manufacturing process including equipment and utensils to be used.

(4) The registrant must dispose of sewage through an approved facility that is:

(a) a public sewage treatment plant; or

(b) an individual sewage disposal system that is operated according to law.

(5) The recipe for each product must be submitted with the application for review and kept on file at the cottage food operation location. Ingredient lists are subject to public disclosure, but recipes are proprietary and are not subject to public disclosure.

(6) At the time of registration, the registrant must demonstrate that the water for the cottage food operation is either:

(a) from an approved public water system; or

(b) meets minimum drinking water standards from a certified laboratory by providing results for total coliform and nitrates from the private well serving the domestic residence that is being registered for the cottage food operation;

(i) nitrates must be below 10 mg/L from a sample within the last 12 months;

(ii) total coliforms must be absent from a sample within the last 6 months;

(iii) failure to meet minimum drinking water standards will result in registration being withheld until samples are provided that meet the minimum nitrate and total coliform standards in this rule.

(c) Water sampling may also be required by the state or local health authority when cottage food is suspected of being associated with an illness or outbreak.

(7) A registration fee of \$40.00 must be paid to the county in which the cottage food operation is registered. Once registered a cottage food operator may sell their registered products anywhere in the state of Montana. The cottage food operation must register again with the local health authority and pay the registration fee if it wishes to change the location of its cottage food operation or produce new products. Recipe changes to an existing approved product that necessitate redetermination as to whether that product constitutes a non-potentially hazardous food or contains a major allergen are new products for the purposes of this rule.

While not exhaustive, the following are examples of when a new fee must be paid:

(a) when a cottage food operator moves to a new house;

(b) when a cottage food operator changes a recipe in a way that may make the recipe potentially hazardous or adds an allergen, such as switching from a traditional frosting to one that contains cream cheese or adding walnuts to chocolate chip cookies; and

(c) when a cottage food operator wishes to make a completely new product, such as dried fruit when they had previously registered chocolate chip cookies.

(8) A department-approved certificate of registration will be provided to each new registrant. A certificate of registration must be made available to a local health authority upon request when a cottage food operator is vending to the public.

NEW RULE X ENFORCEMENT AND INSPECTIONS (37.110.50X) (1) Cottage food operations will be inspected according to the requirements of 50-50-301(3), MCA.

(2) Cottage food operators in violation of this subchapter are subject to enforcement action in accordance with Title 50, chapter 50, part 1, MCA.

NEW RULE XI SAMPLES (37.110.50X) (1) A cottage food operator must furnish cottage food product or ingredient samples for analysis upon request of the regulatory authority when the food is suspected of being associated with an illness or outbreak.

37.110.238 LICENSES (1) and (2) remain the same.

(3) Except for temporary food establishment permit fees set by the local health authority in accordance with 50-50-205(6), MCA, license fees are:

(a) \$85 for each license issued to an establishment that does not have more than two employees working at any one time; and

(b) \$115 for establishments with more than two employees.

(3) through (13) remain the same, but are renumbered (4) through (14).